UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

LAURA MAIETTA and WESLEY WILSON III, Plaintiffs, v. C. R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC., Defendants.	:	CIVIL ACTION NO. 2:19-cv-04170-MMB

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' OMNIBUS MOTIONS *IN LIMINE* TO EXCLUDE PREJUDICIAL EVIDENCE

Plaintiffs move to exclude evidence and argument concerning (a) FDA's 510(k) Clearance of Bard's Recovery® Filter, (b) FDA's December 1996, Cardiovascular Intravascular Filters Reclassification Memorandum ("Price Memo") (Dkt. 68-1), and (c) the 2008 Surgeon General's Call to Action. Judge Campbell admitted this evidence in all of the MDL bellwether cases (*see* Dkt. 7 at 21-22, 29, 56), and other district courts (including those applying Pennsylvania law) denied similar motions. This Court should likewise deny Plaintiffs' Motions because:

- Plaintiffs fail to acknowledge Pennsylvania law, including from the Pennsylvania Supreme Court, holding that evidence of a defendant's compliance with government regulations is relevant to demonstrate due care, which is directly at issue for Plaintiffs' remaining negligence and punitive damages claims. Instead, Plaintiffs inexplicably challenge the relevance of FDA clearance evidence to "strict liability" actions despite conceding that "this Court has ruled out strict liability." (Dkt. 134 at 13-18; Dkt. 113.) As the MDL court and other remand courts (including two applying Pennsylvania law) have found, FDA's clearance of Bard's IVC filters is highly relevant to Plaintiffs'

negligence and punitive damages claims, and its admission will not confuse the jury, unfairly prejudice Plaintiffs, or lead to a mini-trial.

- The Price Memo is directly relevant to whether Bard negligently warned about or designed the Recovery Filter, including whether it is "too harmful to be used by anyone." Moreover, the MDL court already addressed and rejected many of Plaintiffs' arguments, and stated that it "cannot conclude that admission of the reclassification memo will unfairly prejudice Plaintiffs."
- The Surgeon General's Call to Action provides valuable insight into the risks and benefits associated with IVC filters generally and the medical community's understanding of those risks and benefits. The Surgeon General's report is relevant to the risk-benefit analysis required under Pennsylvania law for Plaintiffs' remaining claims and, as recognized by the MDL court, does not confuse the jury or unfairly prejudice Plaintiffs.[1]

For each of these reasons, and those below, Plaintiffs' Motion should be denied.

I. FACTUAL BACKGROUND

A. Regulatory Background Concerning IVC Filters.

Bard's Recovery Filter is a Class II medical device that FDA cleared before Bard was permitted to market the device. FDA's mission, carried out in relevant part by its regulatory review

[1] Bard recognizes that the 2008 Call to Action post-dates the implant of the Recovery Filter and that it filed a motion *in limine* to exclude evidence post-dating the sale of the subject filter. To the extent the Court recognizes a post-sale duty under Pennsylvania law, the Call to Action should not be excluded from trial for the reasons stated herein. However, in the event the Court agrees with Bard that no such post-sale duty exists, then the Call to Action, along with all other post-sale evidence encompassed by that motion *in limine*, should be excluded as irrelevant.

of products, is to ensure that devices cleared for market are both safe and effective, and that they are accompanied by appropriate warnings. While the level of regulatory review may vary depending on the class of product, it is fundamentally wrong to suggest that the 510(k) process does not consider safety and effectiveness. According to FDA, "***the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review***."[2] "The FDA grants 510(k) clearance only where the device 'is as safe and effective as a [predicate device] and does not raise different questions of safety and efficacy than the predicate device.' Safe Medical Devices Act of 1990 ['SMDA']." *In re Bard IVC Filters*, 289 F. Supp. 3d at 1048. "The SMDA did introduce safety and effectiveness considerations into 510(k) review," even if the standard for those considerations is comparative. *Id.*, No. MDL 15-02641-PHX DGC, 2017 WL 5625547, at *7 (D. Ariz. Nov. 22, 2017), *aff'd*, 969 F.3d 1067 (9th Cir. 2020).

FDA originally classified IVC filters as Class III devices. *See* 45 Fed. Reg. 17736 (FDA Feb. 5, 1980). As the Price Memo explains, in 1995, FDA required IVC filter manufacturers to submit summaries of known safety and effectiveness information for FDA to determine whether to reclassify the devices. (Dkt. 68-1 at 2-3.) On December 2, 1996, FDA identified all known safety and efficacy concerns for IVC filters and found, "[a]lthough these risks are potentially life threatening, as is the disease they are intended to treat, they are well known to the users and are well characterized in the medical literature." (*Id.* at 4, 5-8.) FDA also identified the competing benefits of IVC filter use. (*Id.* at 8-9.)

Weighing those benefits against risks, FDA concluded "the use of [IVC filters for the FDA-

[2] **Ex. 1,** FDA Guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," issued July 28, 2014, at 6.

cleared indications] does not present a potential unreasonable risk of illness and injury, and that special controls would ***provide reasonable assurance of the safety and effectiveness of the device***." (*Id.* at 4-5 (emphasis added).) "Special controls in the form of standardized labeling and a device [Guidance] on vena cava filters . . ., in addition to general controls, ***provide reasonable assurance of the safety and effectiveness of the device***." (*Id.* at 4 (emphasis added).) Thus, FDA concluded, "based on publicly available, valid scientific evidence, the [IVC] filter can be regulated as a Class II device (general and special controls) to ***reasonably assure that the device is safe and effective for its intended use***." (*Id.* at 9 (emphasis added).) And in a final rule dated March 31, 2000, *see* 65 Fed. Reg. 17138, 17144 (FDA Mar. 31, 2000), FDA down-classified IVC filters from Class III to Class II, amending 21 C.F.R. § 870.3775 and incorporating special controls, including an FDA Guidance document entitled "Guidance for Cardiovascular Intravascular Filter 510(k) Submission," that was intended to identify important preclinical tests and clinical design considerations for these devices. (Dkt. 93-6.)

B. The Regulatory Record for Bard's Recovery Filter.

The regulatory record for Bard's IVC filters—including Recovery—shows that FDA considered the safety and efficacy of Bard's IVC filters before clearing them. For example, for Recovery, FDA mandated specific revisions to the labeling to include language warning that "the safety and effectiveness of the Recovery Filter for use as a retrievable or temporary filter have not been established," which Bard did as described below.[3] FDA cleared the Recovery Filter, including its warnings, for permanent use on November 27, 2002.[4]

[3] *See* **Ex. 2,** October 4, 2002, Letter from FDA to IMPRA (a subsidiary of Bard); November 27, 2002, FDA Clearance Letter (Dkt. 79-4).
[4] *See* November 27, 2002, FDA Clearance Letter (Dkt. 79-4).

Additionally, given FDA's concerns about the safety of retrievability of the Recovery Filter, it required the submission of clinical data supporting "the safety and effectiveness" of retrievability before it would clear a retrievable indication.[5] Accordingly, a clinical study regarding retrievability of the Recovery Filter was conducted by Dr. Murray Asch, and Bard submitted this clinical data with a new 510(k) submission.[6] Part of that clinical data submission included filter fracture and migration events observed during the study. FDA reviewed the submission and again determined it required additional information and further revisions of the labeling—including requiring that the clinical data be added to the labeling—before it would clear the device.[7] Bard complied with each request, and specifically included the following language that FDA amended and "agreed upon" regarding the filter fracture in the clinical experience section of the Recovery Filter labeling:

> The only other adverse event reported was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, minus the hook.[8]

Notably, the Recovery labeling states under "Precautions" that "[t]he filter should be placed in the suprarenal position in pregnant women and in women of childbearing age."[9] Bard also discussed

[5] *See* **Ex. 3,** December 10, 1999, Letter from FDA to NMT.
[6] *See* April 25, 2003, Recovery Filter 510(k) Submission (Dkt. 79-5 at 24-30) (summarizing Asch clinical trial).
[7] *See* **Ex. 4**, July 1, 2003, Email from FDA to Bard; **Ex. 5**, July 23, 2003, Email from FDA to Bard; *see also* **Ex. 6**, July 22, 2003, FDA Internal Review Memorandum (demonstrating FDA's internal review of retrievability testing); **Ex. 7**, July 25, 2003, FDA Internal Review Memorandum (demonstrating FDA's internal deliberations before recommending clearance).
[8] *See* **Ex. 5**, July 23, 2003, Email from FDA to Bard; **Ex. 8**, Recovery Filter Instructions for Use.
[9] **Ex. 8**, Recovery Filter Instructions for Use

this filter fracture event in its 510(k) submission to the FDA.[10] After review of this submission and labeling, FDA cleared the Recovery, including its warnings, for retrievability on July 25, 2003.[11]

Further, FDA was heavily involved in post-market review and revisions of the Recovery Filter labeling. The timing of FDA's regulatory review of Bard's proposed warning changes is highly probative in this case. Although Plaintiff was of childbearing age at the time of implant on October 3, 2003, her Recovery Filter was placed in an infrarenal position, ***not*** a suprarenal position as instructed. (*See* Dkt. 68, ¶¶ 88-89.) Plaintiff later became pregnant and gave birth in 2013 while the filter was in place, and later learned that her filter had fractured in April 2016. (*Id.* at ¶¶ 64, 88, 101.) As of the date of Plaintiff's implant in October 2003, Bard had not yet received any commercial or field complaint of Recovery Filter fracture. Bard was only aware of the unique filter fracture event during the Asch clinical study involving a pregnant woman implanted in her third trimester. Bard later received the first commercial report of a Recovery filter fracture on December 22, 2003, five months after clearance and more than two months after Plaintiff received her device.

As part of its post-market surveillance of the Recovery, Bard conducted appropriate investigations and communicated with FDA and physicians about the commercial performance of the device. On September 17, 2004, for example, Bard contacted FDA about its intent to issue revised labeling to include warnings about fracture and migration and a Dear Doctor Letter ("DDL") to inform doctors of those changes; and on September 28, 2004, Bard sought guidance from FDA on the language of the proposed labeling and DDL, and whether a new regulatory filing

[10] *See* April 25, 2003, Recovery Filter 510(k) Submission (Dkt. 79-5 at 24-30) (summarizing Asch clinical trial); *id.* at 260 (clinical notes for patient number 33, who experienced filter fracture).

[11] *See* July 25, 2003, FDA Clearance Letter, *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf3/K031328.pdf (last accessed Oct. 5, 2022).

would be required before they could be issued.[12] FDA agreed Bard should submit to FDA the proposed DDL and labeling, and an analysis of complication rates, so FDA could decide whether a new 510(k) submission would be required,[13] all of which Bard submitted on October 5, 2004.[14]

During this time period, Bard and FDA actively discussed the safety and efficacy of the Recovery Filter, as evidenced by internal FDA emails describing members of FDA independently reviewing the clinical performance of the Recovery Filter.[15] FDA ultimately stated the proposed labeling and DDL on November 30, 2004 was "acceptable," without the need for a new 510(k) submission, provided that Bard incorporated specific FDA revisions, which Bard did.[16] Bard began distributing the DDL informing physicians of the label changes in December 2004.

C. The Surgeon General's Call to Action.

In 2008, the Department of Health and Human Services published "The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism." ("Call to Action") (Dkt. 134-1.) The Call to Action provided "vital information on critical health problems that cause enormous health consequences and numerous deaths in our country." (*Id.* at 10.) The authors explained that "[e]stimates suggest that at least 350,000, and as many as 600,000, Americans each year contract DVT/PE, and at least 100,000 deaths are thought to be related to these diseases each year." (*Id.*) The Call to Action represented "an opportunity for multiple stakeholders to come together in a coordinated effort to reverse the projected trends and to dramatically reduce the pain and suffering caused by DVT and PE." (*Id.* at 8.) Preceded by a 2006 workshop, the authors

[12] *See* **Ex. 9**, September 28, 2004, FDA Contact Report.
[13] *Id.*
[14] *See* **Ex. 10**, October 5, 2004, Letter from Bard to FDA.
[15] *See* **Ex. 11**, November 10, 2004, Internal FDA email chain.
[16] *See* **Ex. 12**, November 30, 2004, Letter from FDA to Bard.

identified a "tremendous gap in understanding and knowledge" that they sought to address by "disseminat[ing] information more widely about the availability of effective interventions to prevent and treat DVT/PE." (*Id.* at 10.)

In the section describing the reduction of the risk for DVT and PE, the authors discussed the role of permanent or retrievable implantable filters in the inferior vena cava. (*Id.* at 26.) They explained that IVC filters "have been used with success in a variety of patients, including those whose anticoagulation therapy must be stopped due to the need for urgent surgery, patients undergoing bariatric surgery, and patients who suffer multiple injuries from a motor vehicle accident." (*Id.*)

II. ARGUMENT

A. FDA's 510(k) Clearance of Bard's Recovery Filter is Relevant and Admissible.

Plaintiffs' remaining claims are for negligence (design, warnings, misrepresentation), fraud, and punitive damages. (*See* Dkts. 112, 113 (dismissing strict liability claims).) The issues presented in Plaintiffs' Motion were decided under substantially similar facts and law in the MDL. *See In re Bard IVC Filters Prods. Liab. Litig.*, 289 F. Supp. 3d 1045 (D. Ariz. 2018). Applying Georgia law, which governed the first two bellwether trials (*Booker* and *Jones*), Judge Campbell found Bard's compliance with federal regulatory standards, such as FDA's 510(k) clearance process, is relevant to negligence and punitive damages claims because it is "relevant to the reasonableness of Bard's conduct" and whether Bard "acted with conscious indifference to the dangers posed by its device." *Id.* at 1047; (*see* Doc. 7 at 21-22 (discussing relevance to "negligent

design and punitive damages claims").[17]

Subsequently, two district courts on remand, including Judge Pratter of this District, applied the same reasoning and reached the same result under Pennsylvania law to the same negligence and punitive damages claims at issue in this case. *See Keen v. C. R. Bard, Inc.*, 480 F. Supp. 3d 646, 649-51 (E.D. Pa. 2020) (denying similar motion *in limine* after finding FDA 510(k) clearance evidence "relevant to the claims Mr. Keen brings under Pennsylvania law" for negligence (including design, warnings, and misrepresentation), "as well as the punitive damages he seeks"); **Ex. 13,** Pretrial Conf. Tr. 23:14–25:16, 42:17-53:5, *Peterson v. C. R. Bard, Inc.*, No. 3:19-cv-01701-MO, Dkt. 161 (D. Or. April 20, 2021) ("I'm not going to keep out references to clearance of Bard IVC filters by the FDA" in case involving negligent design and failure to warn under Pennsylvania law).

Indeed, Plaintiffs ignore that Judge Campbell considered extensive briefing on this very issue and admitted this evidence in all of the MDL bellwether cases;[18] they ignore that this evidence was admitted in the *Peterson* trial under Pennsylvania law that reached verdict; and they attempt to distinguish *Keen* on the erroneous basis that this is "a different case"—a Recovery "negligence case"—and "this Court has ruled out strict liability." (Dkt. 134 at 13-14.) But the *Keen* court also dismissed strict liability; only "Mr. Keen's negligence and negligent misrepresentation

[17] Judge Campbell also held in the third bellwether trial (*Hyde*) involving negligent design and punitive damages claims under Wisconsin law that Bard "will not be precluded from presenting evidence of the FDA's 510(k) clearance process." *In re Bard IVC Filters Prods. Liab. Litig.*, No. CV-16-00893-PHX-DGC, 2018 WL 4279833, at *2 (D. Ariz. Sept. 7, 2018).

[18] Plaintiffs do not even direct this Court to any of the MDL court's relevant decisions. They instead cite the appellate decision on the MDL court's separate, unrelated preemption ruling, and leave the misimpression that the MDL Court found 510(k) clearance evidence relevant "in the *Booker* bellwether trial" only to "Booker's punitive damages claims." (Dkt. 134 at 10 (citing *Booker v. C. R. Bard, Inc.*, 969 F.3d 1067 (9th Cir. 2020)).)

claims survived summary judgment, and the Court reserved [ruling on] punitive damages." 480 F. Supp. 3d at 649. These are the very claims at issue in this case. Plaintiffs also ignore that other district courts that have tried Bard IVC filter cases on remand have followed Judge Campbell's decision and admitted evidence regarding the FDA 510(k) review process and evidence of FDA's review and clearance of the warnings, including in Recovery Filter cases.[19]

As demonstrated more fully below, this evidence is highly relevant, and admission will not result in either jury confusion, mini-trials, or unfair prejudice to Plaintiffs. But exclusion of this evidence will result in severe prejudice to Bard.

i. FDA's clearance of the Recovery Filter is relevant under Pennsylvania law.

Evidence of FDA's regulatory review and clearance of the Recovery, and specifically Bard's warnings that accompany it, as well as Bard's compliance with those regulatory standards, while not dispositive, is relevant to Plaintiffs' negligence claims under Pennsylvania law because it goes directly to the reasonableness of Bard's conduct in bringing the filter to the market and

[19] *See, e.g.*, *Johnson v. C. R. Bard, Inc.*, No. 19-CV-760-WMC, 2021 WL 2070448, at *13 (W.D. Wis. May 24, 2021) (reserving ruling, but later permitting this evidence of FDA clearance at trial); *Ocasio* v. *C. R. Bard, Inc.*, No. 8:13-CV-1962-CEH-AEP, 2021 WL 2787993, at *4 (M.D. Fla. July 5, 2021) ("[T]he Court is inclined to find the evidence and testimony related to the 510(k) process to be relevant and not unduly prejudicial," deferring ruling until trial, and later permitting this evidence); *see also Couturier v. Bard Peripheral Vascular, Inc.*, No. CV 19-12497, 2021 WL 3187368, at *3 (E.D. La. July 28, 2021) ("Evidence of regulatory clearance and absence of FDA approvement process of the Eclipse device is relevant and likely probative"); *Laloli v. C.R. Bard, Inc.*, No. 19-CV-05679-JST, 2021 WL 3141190, at *3–4 (N.D. Cal. July 25, 2021) ("Bard can introduce evidence regarding the FDA 510(k) process," but not lack of FDA enforcement action because purported absence of California law); **Ex. 14**, Pretrial Conf. Tr. 136:11-140:25, *Conn, et al. v. C. R. Bard, Inc.*, Case No. 4:14-cv-00298-ASN (S.D. Tex. Oct. 8, 2021) ("I'm going to deny the motion as to the clearance by the FDA" in G2 case); Hearing Tr. 9:4-7, *Branch, et al. v. C. R. Bard, Inc., et al.*, Case No. 3:19-cv-2130-S (N.D. Tex. July 27, 2020) (denying the plaintiff's motion *in limine* to exclude FDA regulatory evidence (Dkt. 98) in Recovery filter cases, "for the reasons articulated in the defendants' response") (Dkt. 77-5)).

providing the warnings that it did when it did. *See Keen*, 480 F. Supp. 3d at 650 (citations omitted) ("[E]vidence of Bard's compliance with FDA regulations and the FDA's clearance of [Bard's] filters, while not dispositive, is relevant to the [negligence] claims Mr. Keen brings under Pennsylvania law. . . . A factfinder, after taking into consideration the history of the FDA's 510(k) clearance of [Bard's] filters, could determine that Bard took reasonable and appropriate steps in its effort to bring the [Bard] filter to market."); **Ex. 13**, *Peterson* Pretrial Conf. Tr. 23:14–25:16, 42:17-53:5; *Bourgeois v. Snow Time, Inc.*, 242 A.3d 637, 658 (Pa. 2020) ("Compliance with the statute or regulation is admissible as evidence of the actor's exercise of due care, but such compliance 'does not prevent a finding of negligence where a reasonable [person] would take additional precautions.'"); *Lance v. Wyeth*, 85 A.3d 434, 456 (Pa. 2014) (acknowledging Pennsylvania's "respect for the FDA and its ongoing efforts to protect the health of the citizenry[, which] is reflected in the practice of Pennsylvania courts permitting defendants to adduce evidence of compliance with governmental regulation in their efforts to demonstrate due care (when conduct is in issue)."); *Birt v. Firstenergy Corp.*, 891 A.2d 1281, 1290 (Pa. Super. 2006) ("[E]vidence of industry standards and regulations is generally relevant and admissible on the issue of negligence.").

Further, Bard's compliance with FDA regulations and industry standards is relevant to the issue of punitive damages. *See Keen*, 480 F. Supp. 3d at 650 (citations omitted) ("[E]vidence of Bard's compliance with FDA regulations and the FDA's clearance of [Bard's] filters, while not dispositive, is relevant to the claims Mr. Keen brings under Pennsylvania law, as well as the punitive damages he seeks."). Punitive damages may be awarded under Pennsylvania law for conduct that is outrageous, because of a defendant's "evil motive or reckless indifference to the

rights of others." *Phillips v. Cricket Lighters*, 883 A.2d 439, 445 (Pa. 2005). "Compliance with industry standard and custom tends to support the defense that [defendant] acted with a nonculpable state of mind, and would negate an inference of wanton indifference to the rights of others. Accordingly, such evidence is material and admissible to refute [plaintiff]'s claim for punitive damages." *Nigro v. Remington Arms Co.*, 637 A.2d 983, 990 (Pa. Super. 1993), *abrogated on other grounds by Aldridge v. Edmunds*, 750 A.2d 292 (Pa. 2000); *Sansom v. Crown Equip. Corp.*, No. 2:10-CV-958, 2011 WL 13147424, at *5 (W.D. Pa. Aug. 11, 2011) (finding "compliance with industry standards and custom weighs against Plaintiffs' argument of a culpable state of mind to underpin a demand for punitive damages, and further negates an inference of wanton indifference to the rights of others."); *see also In re Bard IVC Filters*, 289 F. Supp. 3d at 1047 (applying Georgia law) (finding under similar standard that "[c]ompliance with federal regulations is not sufficient to preclude an award of punitive damages, but it is probative of whether the manufacturer acted with conscious indifference to the dangers posed by its device.").

Here, just as the MDL Court found under Georgia and Wisconsin law and the *Keen* and *Peterson* courts found under Pennsylvania law, evidence of FDA's regulatory review of information exchanged between Bard and FDA (including warnings), Bard's compliance with that regulatory process, and FDA's decision to clear the Recovery and warnings, is relevant. *See In re Bard IVC Filters*, 289 F. Supp. 3d at 1047-48; *Keen*, 480 F. Supp. 3d at 650-51; **Ex. 13**, *Peterson* Pretrial Conf. Tr. 23:14–25:16, 42:17-53:5. Indeed, this evidence is critical for the jury to evaluate whether Bard acted reasonably and with due care in bringing the Recovery to market with the design and FDA-cleared warnings at issue, or whether Bard acted with wanton indifference to the rights of others. And this evidence is essential to the jury's understanding of why Bard's warnings

were as they were at the time of Plaintiff's implant in October 2003, and why Bard later updated the labeling and issued a DDL warning about filter fracture following FDA's revisions and agreement of the labeling changes in November 2004—to the extent any narrow post-sale duty exists in this case, which Bard vigorously disputes in its motion *in limine* on post-implant evidence (*see* Dkt. 141).

ii. Plaintiffs overstate the decisions of two Pennsylvania courts relying on rulings from other Circuits and applying New Jersey law.

Although Plaintiffs cite a decision by the Pennsylvania Superior Court, relying in turn on decisions from the Fourth Circuit and other Circuits, involving an entirely different product line (surgical mesh) with a less robust regulatory record, none of those cases applied Pennsylvania law, nor did they hold that evidence related to FDA's 510(k) review could never be relevant in a product liability case. *Cf. Carlino v. Ethicon, Inc.*, 208 A.3d 92, 107 (Pa. Super. Ct. 2019) (analyzing "whether evidence of 510(k) clearance is admissible under New Jersey law").[20] Indeed, *Carlino* applied New Jersey law and merely affirmed, as in the other cases, under the highly deferential "abuse of discretion" standard based on the evidence offered by the defendants in those cases. *Id.* And *Carlino*'s conclusion that FDA 510(k) clearance was not relevant to New Jersey's rebuttable presumption that warnings were adequate if FDA "approved or prescribed" them, relying on cases outside the Third Circuit, *id.* at 108-111, is directly contradicted by the Third Circuit's subsequent decision finding that warnings of a 510(k)-cleared IVC filter *were* subject to New Jersey's

[20] Plaintiffs also claim that *Hammons v. Ethicon, Inc.*, 190 A.3d 1248, 1289 (Pa. Super. Ct. 2018), *aff'd*, 240 A.3d 537 (Pa. 2020), addressed "this issue" of excluding 510(k) clearance evidence, "also decided under New Jersey law." (Dkt. 134 at 11-12.) Not so. The only discussion about 510(k) evidence was in a single footnote and did not relate to any exclusionary ruling, but rather whether FDA's clearance of the surgical mesh products could satisfy the "FDA punitive damage exemption" to the New Jersey Products Liability Act. *Hammons*, 190 A.3d at 1289 & n.15.

presumption because "it is undisputed that the Greenfield Filter is subject to FDA oversight." *Greisberg v. Bos. Sci. Corp.*, No. 21-2364, 2022 WL 1261318, at *2 (3d Cir. Apr. 28, 2022).

Moreover, none of the cases cited by Plaintiffs involved the kind of extensive regulatory history associated with Bard's IVC filters. Those courts may have reached a different result, just as Judge Campbell and Judge Pratter did, had they involved Bard's IVC filters. *See, e.g.*, *Ethicon Physiomesh Flexible Composite Hernia Mesh Prod. Liab. Litig. v. Ethicon, Inc.*, No. CV 1:17-MD-2782-RWS, 2020 WL 9887565, at *9 (N.D. Ga. Nov. 25, 2020) (excluding evidence in surgical mesh case but acknowledging Judge Campbell's decision in "*Bard IVC Filters* involved a different medical device, possibly calling for a different Rule 403 analysis."). FDA's regulatory review of Bard's IVC filters and the warnings that accompany them differs from most 510(k) devices—a history of down classification, FDA-mandated compliance with device-specific special controls, clinical trial and data requirements, specific FDA labeling changes dictated word-for-word, and numerous detailed FDA requests for safety-related information. (*See supra* Factual Background.) This record compels a different result than the cases cited by Plaintiffs because it shows that FDA reviewed the safety and efficacy of the products before clearing them, as illustrated by FDA's own internal review memoranda.

Further, the reasoning in those opinions is contrary to that of many other courts, as discussed herein, including the MDL Court and other courts that have tried Bard IVC filter cases on remand. "Courts generally find evidence of the 510(k) process is relevant but are divided on whether the probative value of the evidence is substantially more prejudicial than probative." *In re Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prod. Liab. Litig.*, 114ML02570RLYTAB, 2018 WL 6617375, at *1 (S.D. Ind. Dec. 18, 2018) (collecting cases and

denying motion). Even as to surgical mesh, one appellate court recently rejected the reasoning in these opinions (including *Cisson* and *Huskey*) and adopted Judge Campbell's approach deeming 510(k) evidence admissible. *See Hrymoc v. Ethicon, Inc.*, No. A-1083-18, 2021 WL 787039, at *1 (N.J. Super. Ct. App. Div. Mar. 2, 2021) (vacating $83 million mesh verdicts, finding exclusion of 510(k) evidence was not fair or appropriate and "was unfairly and repeatedly capitalized upon by plaintiff's counsel at both trials"). This Court should too.

iii. Plaintiffs' reliance on Pennsylvania law finding government and industry standards evidence irrelevant "in strict liability actions" is misplaced.

Plaintiffs spend a significant portion of their argument inexplicably challenging the relevance of FDA clearance evidence and industry standards "in defense of a strict liability action" under Pennsylvania law following *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014), "because the manufacturer's conduct is irrelevant in strict liability." (Dkt. 134 at 14-18.) But as Plaintiffs concede, "this Court has ruled out strict liability," and so their reliance on this authority is misplaced. (Dkt. 134 at 13; Dkt. 113.) Plaintiffs cannot dispute that the jury will be tasked with evaluating the reasonableness of Bard's conduct for their remaining negligence claims. (Dkts. 112, 113.) As the cases cited by Plaintiffs acknowledge, government and industry standards evidence is "relevant to the negligence claims." *Webb v. Volvo Cars of N. Am., LLC*, 148 A.3d 473, 483 (Pa. Super. Ct. 2016). Such evidence "go[es] to the negligence concept of reasonable care," and in a design case in particular "go[es] to the reasonableness of the [manufacturer's] conduct in making its design choice." *Lewis v. Coffing Hoist Div., Duff-Norton Co.*, 528 A.2d 590, 594 (Pa. Super. Ct. 1987); *accord Webb*, 148 A.3d at 483; *Malcolm v. Regal Ideas, Inc.*, No. CV 19-239, 2021 WL 3006653, at *5-6 (E.D. Pa. July 15, 2021) (Baylson, J.) (discussing preclusion of "evidence of a product's compliance with industry standards as irrelevant and inadmissible in a strict liability

action," and finding "evidence of industry standards—a negligence concept—is inadmissible in this strict liability action."). Therefore, the Court should disregard Plaintiffs' misplaced arguments.

iv. FDA's clearance of the Recovery Filter is relevant because safety and efficacy play an important role in 510(k) review.

Plaintiffs here, as in *Keen*, the MDL, and all other remand cases, erroneously "attempt[] to paint the 510(k) clearance process as irrelevant because it is a comparative, rather than definitive, finding by the FDA that a device is safe and effective." *Keen*, 480 F. Supp. 3d at 650. They argue, citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), that the 510(k) process "does not relate to [] product safety." (Dkt. 134 at 9.)

First, Plaintiffs' heavy reliance on *Lohr* is misplaced. *Lohr* involved the question of whether FDA's clearance of a 510(k) device preempts state law product liability claims under 21 U.S.C. §360k(a). *See In re Bard IVC Filters*, 2017 WL 5625547, at *5. "The *Lohr* decision did not, however, address whether evidence concerning FDA 510(k) clearance is admissible or relevant to the reasonableness of a manufacturer's conduct" at issue in negligence and punitive damages claims. *Keen*, 480 F. Supp. 3d at 650. Judge Campbell agreed, concluding that, while the MDL plaintiffs (citing *Lohr*) correctly noted "that the 510(k) process focuses on device equivalence, not device safety[,] this does not render evidence of the 510(k) process irrelevant to the reasonableness of Bard's conduct." *In re Bard IVC Filters*, 289 F. Supp. 3d at 1047-48. Judge Pratter "follow[ed] Judge Campbell's lead in finding references to the 510(k) process to have probative value" to negligence and punitive damages claims under Pennsylvania law and concluded the plaintiff's reliance on *Lohr* was "equally meritless." *Keen*, 480 F. Supp. 3d at 650.

Moreover, Plaintiffs' attempt to graft a "safety" limitation onto the relevance of this evidence is not supported by any controlling authority from the Pennsylvania Supreme Court and

should be rejected. *See id.* at 650 n.4 ("To the extent [plaintiff] suggests that the jury is only to consider compliance evidence and regulations related to 'safety,' the Court rejects such a proposition."). Nevertheless, Plaintiffs' underlying premise is simply false. *See id.*, at 650 (rejecting same argument). Safety and efficacy play an important role in FDA's decision-making in the 510(k) process. "The '[Safe Medical Devices Act of 1990] did introduce safety and effectiveness considerations into 510(k) review,' even if the standard for those considerations is only comparative." *Id.* (quoting *In re Bard IVC Filters*, 2017 WL 5625547, at *7). This is further evidenced by FDA's down-classification of IVC filters, as well as the history of FDA's 510(k) clearance of the Recovery—as illustrated by FDA's own internal review memoranda—which shows that FDA reviewed the safety and efficacy of the device and its warnings before clearance.

v. FDA's clearance of the Recovery Filter is not unfairly prejudicial.

Plaintiffs fail to identify any legitimate basis why they will be prejudiced by evidence of FDA clearance. Plaintiffs' Rule 403 arguments are virtually identical to those considered and rejected by the MDL, *Keen*, and *Peterson* courts. *See In re Bard IVC Filters*, 289 F. Supp. 3d at 1048-49 (the plaintiff's concerns "can be adequately addressed without excluding relevant evidence to the detriment of Defendants."); *Keen*, 480 F. Supp. 3d at 651; **Ex. 13**, *Peterson* Pretrial Conf. Tr. 23:14–25:16, 42:17-53:5. Plaintiffs "certainly will be free to present evidence and argument that the 510(k) process is a comparative one that requires only substantial equivalence to a predicate device." *In re Bard IVC Filters*, 289 F. Supp. 3d at 1049.[21] But "[m]any of the

[21] Bard will not refer to its IVC filters as FDA "approved" at trial. Plaintiffs' concern that they will be prejudiced because of the risk of confusion as to whether Bard filters were FDA-approved as safe and effective can be alleviated, "*if necessary*, by a limiting instruction regarding the nature of the 510(k) process," as Judge Campbell recognized. *In re Bard IVC Filters*, 289 F. Supp. 3d at 1049 (emphasis added). He ultimately ruled a limiting instruction was not necessary at the

relevant facts in this case occurred in the context of FDA 510(k) review, and much of the evidence is best understood in that context." *Id.* "Attempting to remove any references to the FDA from the trial would risk creating a misleading, incomplete, and confusing picture for the jury." *Id.*

Moreover, it is unclear "that all FDA-references could [even] be removed, given that much of the evidence . . . comes from the FDA." *In re Bard IVC Filters*, 289 F. Supp. 3d at 1049. "[I]f the evidence was half-baked, containing some references to the FDA but not explaining what role the FDA played with respect to the Bard filters, the jury would be left to speculate about the FDA's involvement and conclusions." *Id.* This is a real concern in this case, and Bard will be extremely prejudiced "if it is not permitted an opportunity to present to the jury a full picture concerning its decisions to market" the Recovery in 2002 with the FDA-cleared warnings that it did, and to continue marketing it through October 2003 with those warnings when Ms. Maietta received her filter. *Keen*, 480 F. Supp. 3d at 651. During this time period, Bard was in frequent communication with the FDA regarding the performance of the Recovery and later obtained FDA's guidance on proposed revised labeling and a DDL concerning filter fracture, which FDA ultimately approved (subject to incorporation of specific FDA revisions, which Bard made). Removing this evidence creates an uneven playing field, leaving the jury with an incomplete picture concerning this critical history of the Recovery Filter fracture warnings at issue in this case as well as the design history.

The prejudice that Plaintiffs seek to impose on Bard is amplified by the evidence that Bard anticipates Plaintiffs will seek to present at trial: that the Recovery violates FDA regulations and/or federal law based on comparisons to Bard's predicate device, the Simon Nitinol Filter (Bard's

---

bellwether trials because the presentation of the evidence did not present any risk of jury confusion. (*See* **Ex. 15**, *Booker* Trial Tr. 2447:18-19.)

permanent-only filter);[22] that Bard negligently designed the Recovery by failing to implement design improvements from its later-generation filters; and that Bard did not adequately warn Plaintiffs' physicians (especially as to filter fracture) and did not make changes to its warnings. In other words, Plaintiffs would ask this Court to issue an order allowing Plaintiffs to present this evidence to the jury, yet disallowing Bard from presenting evidence regarding the steps it took to demonstrate to FDA that its Recovery Filter should be legally marketed, FDA's multiple

[22] Plaintiffs propose a form of quid-pro-quo, arguing that if the Court allows 510(k) evidence "for any reason, then the Court should prevent Bard from claiming the SNF was not a reasonably safer alternative design" because "[t]he Recovery filter was predicated on the SNF" in the 510(k) submission. (Dkt. 134 at 11.) To the extent that "an alternative design theory" is even "still cognizable as a basis for liability after *Lance*," *Ebert v. C.R. Bard, Inc.*, No. 20-2139, 2021 WL 2656690, at *3 (3d Cir. June 24, 2021), *certified question accepted*, 260 A.3d 81 (Pa. 2021) (certifying question to "the Pennsylvania Supreme Court [which] is best positioned to resolve this question"), Plaintiffs are conflating two distinct concepts: (1) substantial equivalence—a distinct regulatory term-of-art—for 510(k) clearance, and (2) reasonable alternative design for product liability. Whether the Recovery Filter is "as safe and effective as" and, hence, "substantially equivalent" to the SNF for regulatory clearance, 21 U.S.C. § 360c(i)(1)(A), does not mean that the SNF, a permanent-only filter, was a reasonable safer alternative design to the *retrievable* Recovery Filter that Dr. Tortella implanted in his young patient, Ms. Maietta.

FDA recognizes that a new device can be "as safe and effective" as the predicate (and therefore substantially equivalent) even when there are differences in the safety profiles of the devices, especially where "there is an increase in benefit associated with the new device," such as "[w]hen a new device has technological improvements that are important for public health" and warrant "patient access to these innovative technologies." **Ex. 16**, FDA Guidance: Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics (Sept. 25, 2018) at 12, 16. The Recovery is a prime example, as it was the first retrievable IVC filter on the market without a limited 14-30 day window for removal.

On the other hand, although FDA cleared the Recovery Filter as substantially equivalent to the SNF, that does not make the SNF a reasonable safer alternative design for Ms. Maietta under Pennsylvania law. This is because Dr. Tortella wanted a filter "that could be removed if need be." (Dkt. 68, ¶ 33.) The SNF lacks this advantage, which is to be considered in "determining whether an alternative design is reasonable." *Kordek v. Becton, Dickinson & Co.*, 921 F. Supp. 2d 422, 431 (E.D. Pa. 2013) (considering the "relative advantages and disadvantages of the product as designed and as it alternatively could have been designed.").

clearances and post-market review of the device and its warnings, as well as the extensive design, testing, and regulatory clearance processes required before any design changes could be implemented and the regulatory processes that Bard engaged in before any labeling changes could be implemented. The true prejudice comes from excluding this evidence, as it is undeniable that the Recovery, like every other prescription medical device in the United States, could not be marketed without prior FDA review. Without this evidence, the jury will be left to speculate about what happened. This FDA evidence is highly relevant and should be admitted at trial.

vi. FDA's clearance of the Recovery Filter will not result in a mini-trial.

Plaintiffs argue that allowing FDA evidence will result in a mini-trial on 510(k) review and Bard's compliance with FDA regulations. But as evidenced by all three MDL bellwethers and the other remand cases that were tried within strict time limits, these cases can and have been tried without unnecessary delay. Judge Campbell was correctly "convinced that efficient management of the evidence and adherence to the Court's time limits will avoid any risk of unnecessary or time-consuming mini-trials." *In re Bard IVC Filters*, 289 F. Supp. 3d at 1049; *accord Keen*, 480 F. Supp. 3d at 651. The same will be true here and evidence regarding the FDA's regulatory review of the Recovery Filter and its warnings will be a critical part of the story in this case.

B. FDA's Price Memo is Relevant and Admissible.

The Price Memo "provide[s] detail on the known risks associated" with IVC filters, and provides FDA's explanation to "justify the down classification from class III to class II." (Price Memo at 1.) In doing so, the Price Memo provides information that is not only relevant, but also critical to the jury's determination of the issues in this case.

The following is a summary of some of this critical information:

- FDA described the "serious clinical issue" of pulmonary embolism, which, according to FDA, results "in approximately 200,000 deaths annually in the United States" (*id.* at 7);
- FDA outlined the "well known" and "well characterized" risks associated with IVC filters, and published the reported rates of those complications, including filter fracture (2%), migration (up to 53%), caval penetration (9%), and death (up to 4%) (*see id.* at 3, 4-7);
- FDA found that "[a]lthough placement of filters are not without risks, the likelihood of risks occurring is relatively small" (*id.* at 8); and
- Based on FDA's "extensive review of published reports concerning this category of devices, information submitted in reclassification petitions and by manufacturers in response to the published 515(I), a review of [Medical Device Reports], and previously cleared 510(k)s," FDA concluded that IVC filter use "does not present a potential unreasonable risk of illness and injury, and that special controls would provide reasonable assurance of the safety and effectiveness of the device." (*Id.* at 3-4.)

In the Bard IVC Filter MDL, the MDL Plaintiffs moved pursuant to Rules 402 and 403 to exclude the Price Memo, but Judge Campbell denied their motion. *In re Bard IVC Filters*, 2018 WL 4279833, at *2 ("The Court cannot conclude that admission of the reclassification memo will unfairly prejudice Plaintiffs."). Bard respectfully asks this Court to follow Judge Campbell's lead and likewise deny Plaintiffs' Motion that seeks to exclude the Price Memo.

i. The Price Memo is relevant to Plaintiffs' negligent design claim.

Contrary to Plaintiffs' assertion, the above-referenced information in the Price Memo is directly relevant to resolution of Plaintiffs' negligent design claim, including whether Bard placed

the Recovery Filter on the market with actual or constructive knowledge that it was "too harmful to be used by anyone."

Following the Supreme Court's precedent in *Lance*, this Court articulated the Pennsylvania standard for negligent design as follows: "[u]nder Pennsylvania law, pharmaceutical companies violate their duty of care if they introduce a drug into the marketplace, or continue a previous tender, with actual or constructive knowledge that the drug is too harmful to be used by anyone." *Maietta v. C. R. Bard, Inc.*, No. CV 19-4170, 2022 WL 3577374, at *5 (E.D. Pa. Aug. 19, 2022) (quoting *Lance v. Wyeth*, 85 A.3d 434, 461 (Pa. 2014)); *see also Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637, 644 (E.D. Pa. 2020) (applying *Lance* standard to prescription medical device). Thus, "[a] company which is responsible for tendering into the market a drug which it knows or should know is so dangerous that it should not be taken by anyone can be said to have violated its duty of care either in design or marketing." *Lance*, 85 A.3d at 458.

The Price Memo provides context for a jury to understand Bard's decision-making in designing and marketing the Recovery Filter, notwithstanding the known risks associated with ***all IVC filters***, which FDA acknowledges in the Memo. For instance, the rates identified in the Price Memo provide a type of "benchmark" against which the Recovery Filter—and Bard's decisions regarding the same—may be compared and judged. This is particularly important for the jury when assessing Bard's decision to continue to market the Recovery Filter following the completion of the Asch clinical trial, in which (as Bard described to FDA in the 2003 510(k) submission for retrievability) 1 out of 58 patients experienced a filter fracture, and 1 out of 58 patients experienced a filter migration. (*See* Recovery Filter 510(k) (Dkt. 79-5 at 24-30 (summary of Asch clinical trial involving 58 patients); *id.* at 226-227 (clinical notes for patient number 9, who experienced cranial

migration); *id.* at 260 (clinical notes for patient number 33, who experienced filter fracture).) Moreover, the fact that FDA recognized in the Price Memo that all IVC filters carry risks at certain reported rates, yet characterized the "likelihood" (i.e., reported frequency) of those risks as "relatively small," (Price Memo at 8), helps the jury decide whether the Recovery Filter—with reported rates at or below those recognized by FDA—is "too harmful to be used by anyone." *Lance*, 85 A.3d at 461.

Finally, that FDA in the Price Memo concluded that IVC filters as a class of devices—even with reported complication rates such as filter migration up to 53% (Price Memo at 5-6)—do "not present a potential unreasonable risk of illness and injury," (*id.* at 3), is evidence for the jury to consider when deciding whether the Recovery Filter's risks are so allegedly unreasonable that the device can be said to be "too harmful to be used by anyone." *Lance*, 85 A.3d at 461.

ii. The Price Memo is relevant to Plaintiffs' negligent failure-to-warn claim.

The Price Memo is also directly relevant to Plaintiffs' warning claim. In the context of a negligent failure-to-warn claim, "[t]he adequacy of a warning is determined based on what the manufacturer knew, or should have known, about a given risk at the time the patient was prescribed the medical device, and whether the label warned of that risk." *Ebert v. C. R. Bard, Inc.*, 459 F. Supp. 637, 647 (E.D. Pa. 2020). "[A] manufacturer is liable only if he fails to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous." *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984).

One of Plaintiffs' principal arguments to support their failure-to-warn claim is that Bard allegedly knew the Recovery Filter failed at higher rates compared to competitors but failed to warn Ms. Maietta's implanting physician, Dr. Tortella. (*See, e.g.*, Dkt. 80 at 3-4.) To rebut that

assertion, Bard must be permitted to present evidence that shows that FDA recognized the "well known" and "well characterized" risks associated with IVC filters and understood the reported rates for those complications. This is particularly important considering Bard submitted its IFU to FDA as part of its 510(k) submissions, (*see, e.g.*, Dkt. 79-5 at 38-47), and yet FDA did not suggest to Bard that it add comparative rate information in the warning. A jury—armed with that evidence—may then properly judge whether Bard exercised reasonable care—based on what Bard knew or should have known—in formulating its IFU in light of its clinical trial experience (i.e., the Asch study) and commercial experience with Recovery, where fracture, migration, and perforation rates have always been below those reported in the Price Memo.

iii. Plaintiffs' arguments were previously rejected by the MDL Court, and are otherwise without merit.

Plaintiffs argue the Price Memo is allegedly inadmissible because it is not "specific" to the Recovery Filter, or any particular filter at all. (Dkt. 134 at 7-8.) But they ignore the fact that the MDL Plaintiffs raised a similar argument, which Judge Campbell rejected. *See In re Bard IVC Filters*, 2018 WL 4279833, at *2 ("Plaintiffs seek exclusion of the FDA's 1996 reclassification memo because it does not directly relate to . . . any Bard retrievable filter."). Judge Campbell found that "the memo explains why IVC filters are subject to 510(k) review instead of the premarket approval process." *Id.*

The Price Memo is also necessary evidence to rebut Plaintiffs' allegation that Bard "bypass[ed]" the FDA's more stringent premarket approval requirements by submitting a 510(k) application to obtain FDA clearance to market the Recovery Filter. (Dkt. 79 at 2, ¶ 1 ("[A] manufacturer seeking to market a new medical device may attempt to bypass the FDA's normal premarket approval process by submitting a '§ 510(k) notification.'"); *id.* at 5, ¶ 3 ("Plaintiffs deny

that a manufacturer may not choose a different premarket regulatory pathway as stated" and suggesting that Bard chose its regulatory pathway).) Again, Plaintiffs fail to acknowledge that the Judge Campbell specifically found that the Price Memo "tends to rebut Plaintiffs' argument that Bard strategically chose the easier path of clearance instead of approval." *In re Bard IVC Filters*, 2018 WL 4279833, at *2.

Finally, Plaintiffs suggest the Price Memo is irrelevant because it "predates the existence of retrievable filters" and is thus irrelevant to "any retrievable IVC filter." (Dkt. 134 at 7-8.) This argument is without merit for two reasons. First, Plaintiffs ignore that the Price Memo is addressing IVC filters ***as a class of medical devices***. All IVC filters—permanent and retrievable—are classified under the same Code of Federal Regulations Section. (*See* 21 C.F.R. § 870.3375; *see also* Price Memo at 1 (referencing 21 C.F.R. § 870.3375); FDA Clearance Letter for Recovery Filter (Dkt. 79-4) (noting "Regulation Number" for Recovery Filter is 870.3375).)

Second, the Price Memo was issued when IVC filters had a permanent only indication, and Plaintiffs themselves repeatedly describe the Recovery Filter as a "permanent" filter. (*See, e.g.*, Pls.' Resp. to MSJ (Dkt. 80), at 2 ("This device was marketed and sold as a *permanent, lifetime* implant with the option of being able to retrieve it at any time in the future." (emphasis in original).) Thus, to the extent the relevance of the Price Memo turns on the FDA cleared indications for an IVC filter, as Plaintiffs suggest, the Memo applies to the Recovery Filter.

iv. Plaintiffs will not be unfairly prejudiced by admission of the Price Memo.

Plaintiffs raise a Rule 403 argument, but their allegations largely relate to relevance—i.e., arguing that admission of the Price Memo may lead a jury to evaluate it "as if it is relevant to 1) Bard's internal processes and conduct relevant to this case, 2) any retrievable IVC filter, and; 3)

the filter Ms. Maietta received (the Recovery)." (Dkt. 134 at 8.) As explained above, the Price Memo ***is relevant*** to retrievable IVC filters, including Recovery, and it is relevant to Plaintiffs' negligence claims. Thus, admission of the Price Memo would not be "misleading" in these regards under Rule 403.

To the extent Plaintiffs suggest that the Price Memo "can be used as a quasi-government blessing of IVC devices" and that such appearance of blessing is misleading or prejudicial, Plaintiffs' argument is unfounded for two reasons. First, FDA itself concluded that IVC filters, as a class of devices, "do[] not present a potential unreasonable risk of illness and injury." (Price Memo at 3.) Whether this is a "blessing" by FDA or not, it is an important piece of information for the jury to evaluate whether the Recovery Filter (with its attendant low complication rates) is "too harmful to be used by anyone." *Lance*, 85 A.3d at 461.

Second, if Plaintiffs believe Bard or its counsel are mischaracterizing the import of the Price Memo such that Plaintiffs may be prejudiced, they may object at trial or request a limiting instruction. But on the issue of prejudice, Judge Campbell said that he "cannot conclude that admission of the reclassification memo will unfairly prejudice Plaintiffs." *In re Bard IVC Filters*, 2018 WL 4279833, at *2. Bard respectfully asks this Court to reach the same conclusion and deny Plaintiffs' Motion.

C. The Surgeon General's 2008 Call to Action is Relevant and Not Prejudicial.

Plaintiffs seek to exclude the 2008 Call to Action and, as prior plaintiffs have argued, contend that the Call to Action is irrelevant and unduly prejudicial. (Dkt. 134 at 4-7.) Indeed, these same arguments were raised in the MDL, and the Call to Action was admitted in all three MDL bellwether trials. Although the MDL plaintiffs did not file motions *in limine* to exclude the Report in the first two trials, *Booker* and *Jones*, it was admitted over various objections. (**Ex. 17**, *Booker*

Trial Tr. 2052:15 – 2054:2; **Ex. 18**, *Jones* Trial Tr. 2310:1-19.) As a result, the only written order by Judge Campbell occurred in the third trial, *Hyde*. *In re Bard IVC Filters*, 2018 WL 4279833, at *2-*3 (holding that "the Court cannot conclude that admission of the Call to Action report will confuse the jury or unfairly prejudice [p]laintiffs"). Since that time, remand courts considered similar motions and denied attempts to exclude evidence of the Call to Action from being presented to juries.[23] Plaintiffs' complaints of prejudice echo their arguments to exclude evidence of FDA's

[23] *Couturier. v. C. R. Bard, Inc.*, No. 2:19-cv-12497-ILRL-DP, 2021 WL 3187368, at *2 (E.D. La. July 28, 2021) (denying the motion, but "precluding argument that the evidence at issue was an endorsement of [Bard's] product"—an argument Bard does not seek to raise here either); *Workmaster v. C. R. Bard, Inc.*, No. 6:19-cv-2036-PGB-GJK, 2021 WL 3709166, at *2 (M.D. Fla. July 26, 2021); *Laloli v. C. R. Bard, Inc.*, No. 19-cv-05679-JST, 2021 WL 3141190, at *3 (N.D. Cal. July 25, 2021) ("The Call to Action report is relevant to Plaintiff's negligent design claim because, at the very least, it is relevant to the risk-benefit analysis the jury must perform"); *Ocasio v. C. R. Bard, Inc.*, No. 8:13-cv-1962-CEH-AEP, 2021 WL 2787993, at *7 (M.D. Fla. July 5, 2021) ("the Court finds the Surgeon General's 'Call to Action' is relevant to the availability of treatment options and the risk/benefit analysis"); *Johnson v. C. R. Bard, Inc.*, No. 3:19-cv-00760-wmc, 2021 WL 2070448, at *13-*14 (W.D. Wis. May 24, 2021) (citing *Hyde* and denying plaintiff's motion because the report is "relevant to plaintiff's claim that the filter was not reasonably safe, which necessarily involves a risk-benefit analysis" and because "the report itself does not present any risk of unfair prejudice to the plaintiff").

Bard notes that two Courts have considered similar motions and granted them. The first, the Northern District of Texas, granted the motion on four separate occasions. *Brown v. C. R. Bard, Inc.*, No. 3:19-cv-2168, Doc. 197 (N.D. Tex. July 26, 2021) (granting motion to exclude but noting that "[t]he Court's preliminary ruling on the . . . motion[] is not a ruling on admissibility") (**Ex. 19**); *Sweezey v. C. R. Bard, Inc.*, No. 3:19-cv-2172-S, Doc. 335 (N.D. Tex. July 26, 2021) (same) (**Ex. 20**); *Branch v. C. R. Bard, Inc.*, No. 3:19-cv-2130-S, Doc. 249 (N.D. Tex. July 1, 2021) (same) (**Ex. 21**); *Wright v. C. R. Bard, Inc.*, No. 3:19-cv-2176-S, Doc. 262 (N.D. Tex. May 6, 2021) (same) (**Ex. 22**). Despite these preliminary rulings, in the two cases tried to completion, evidence regarding the Call to Action was presented to the jury in each case. (*E.g.*, **Ex. 23**, May 24, 2021 *Wright* Trial Tr. at 51:9-52:24; **Ex. 24**, July 14, 2021 *Branch* Trial Tr. at 4:15-5:3, 35:7-15 (Def. Exh. 239).) The second court to consider the issue, the Middle District of Tennessee, granted the motion but noted that "nothing about [plaintiff]'s motion would prevent any expert from citing or relying on" the underlying "medical literature." *Nolen v. C. R. Bard, Inc.*, No. 3:19-cv-0799, Doc. 188 (M.D. Tenn. May 26, 2021) (**Ex. 25**). Plaintiff dismissed this case before proceeding to trial. As such, Bard is not aware of any trial in which the plaintiff successfully sought to exclude evidence regarding the Call to Action from being presented to the jury.

510(k) clearance process, which they similarly raise again here despite already being rejected by the MDL Court. Further, Plaintiffs seek to exclude evidence of a prominent public health entity recognizing IVC filters as an appropriate treatment option. But Plaintiffs are unable to point to any legitimate prejudice from Bard's limited use of the Call to Action, nor are Plaintiffs able to refute the relevance of the Call to Action to Bard's defenses against Plaintiffs' negligent failure to warn claim.

i. The Call to Action is not unfairly prejudicial to Plaintiffs.

Plaintiff argues that Bard's use of the Call to Action is part of a strategy to mislead the jury by claiming that the Surgeon General considered Bard's IVC filters necessary to treating the disease states described in the Call to Action. The Call to Action is not evidence Bard has manipulated, as Plaintiff suggests, to mislead the jury, but rather is a publicly available document from a reliable source that succinctly speaks to the seriousness of venous thromboembolisms and the importance of prophylactic efforts, like IVC filters. As the MDL Court noted,

> [t]he record does not support Plaintiffs' assertion that Defendants argued during the first two bellwether trials that "Bard acted at the direction of the Surgeon General" and "the Surgeon General considers Bard's IVC filters necessary" to treat pulmonary emboli. If Plaintiffs believe that Defendants are improperly implying the imprimatur of the Surgeon General, they may object at trial. But the Court cannot conclude that admission of the Call to Action report will confuse the jury or unfairly prejudice Plaintiffs.

In re Bard IVC Filters, 2018 WL 4279833, at *3 (citations omitted). Plaintiffs continue to use the "straw-man" of alleged misdirection by Bard at trial because there is no legitimate basis to exclude the Call to Action. Indeed, the Third Circuit has relied upon such reports in the past. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 272 n.2 (3d Cir. 2017) (relying on the 2004 "Bone Health and Osteoporosis: A Report of the Surgeon General"), *vacated on other*

grounds sub nom. Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019).

ii. To the extent the Court recognizes a post-sale duty to warn, the Call to Action is relevant to Plaintiffs' negligent failure-to-warn claim.

As it was published after Plaintiff was treated with the Recovery Filter, the Call to Action is relevant to only the post-sale duty to warn analysis, to the extent one exists under Pennsylvania law. To assert a viable negligent failure to warn claim under Pennsylvania law, "a plaintiff must allege facts sufficient to plausibly show that the defendant failed to exercise reasonable care to inform those for whose use the product is supplied of the facts which make it likely to be dangerous." *McGrain v. C.R. Bard, Inc.*, 551 F. Supp. 3d 529, 542 (E.D. Pa. 2021) (citations omitted). As explained more fully in Bard's motion *in limine* regarding post-sale evidence, the post-sale duty to warn is limited to the manufacturer's knowledge of latent defects. *Walls v. Medtronic, Inc.*, No. CV 19-3690, 2019 WL 6839942, at *4 (E.D. Pa. Dec. 16, 2019) (noting "[w]hether Plaintiffs can establish such a claim is not squarely before me based on the Complaint here, but it should be noted that any post-sale duty to warn under Pennsylvania law is extremely narrow, *Walton v. Avco Corp.*, 610 A.2d 454, 459-60 (1992), and could be preempted even if Pennsylvania sought to impose such a duty on pharmaceutical suppliers. *Riegel*, 552 U.S. at 330"); *see Inman v. Gen. Elec. Co.*, No. 2:11CV666, 2016 WL 5106939, at *7 (W.D. Pa. Sept. 20, 2016); *DeSantis v. Frick Co.*, 745 A.2d 624, 630–31 (Pa. Super. Ct. 1999). The Call to Action includes references to 97 different pieces of medical literature collected by the Surgeon General's office, many of which pre-date Plaintiff's implant. It reflects the knowledge of health care providers and governmental public health entities (1) prior to implant and evidences the fact that the complications experienced by Plaintiff were known to the medical community at that point; (2) after implant and reflect no material change in the community's understanding of the risks

associated with IVC filters (and, if anything, a greater appreciation of the benefits of the same).

Moreover, the Call to Action is one more piece of evidence to rebut Plaintiff's claims that IVC filters, including Bard's filters, provide no clinical benefit, and are not safe or effective. Indeed, Plaintiffs retained the expert witness, Dr. Garcia, to specifically argue to the jury that anticoagulants are superior to IVC filters to treat PE – ***all*** IVC filters, not just Bard's filters.[24] Plaintiffs' retained experts Drs. Muehrcke and Hurst also dispute the efficacy of IVC filters generally (even though both doctors continue to place IVC filters in patients). (**Ex. 27**, Hurst Report at 17; **Ex. 28**, Muehrcke Report at 18.) The Call to Action speaks to this very issue and, as such, is relevant.

Also, Bard expects that Plaintiffs' central themes at trial will include (1) that the FDA and medical community were unaware of the risks posed by Bard's IVC filters, and (2) that Bard's retrievable filters should have had the same safety profile of permanent filters such as the SNF. The Call to Action provides context to rebutting this assertion, in that the Surgeon General calls for the health care system to further "research the risks and benefits related to permanent versus retrievable placement of IVC filters." (Dkt. 134-1 at 38.) In other words, Plaintiffs ask this Court to allow them to present evidence to the jury that Bard, and only Bard, knew of risks associated

[24] Confusingly, Dr. Garcia relies on medical literature that almost exclusively post-dates Plaintiff's implant. (**Ex. 26**, Reliance List.) Yet Plaintiff suggests the Call to Action should be excluded because it also post-dates Plaintiff's implant. Plaintiff cannot have it both ways. Consistent with Bard's motion *in limine* regarding post-sale evidence, it is Bard's position that all such evidence is irrelevant and should be excluded. In the event the Court disagrees, the Call to Action is equally admissible and Plaintiff does not explain why the fact that that the Call to Action was published in 2008 creates such a meaningful time gap that the Call to Action is rendered irrelevant. Plaintiff cannot seriously dispute that the 100,000 American deaths each year referenced in the Call to Action constituted any less of a public health crisis in 2003 before Plaintiff's implant, than in 2006 during the Surgeon General's workshop, or in 2008 when the Call to Action was eventually published. (Dkt. 134-1 at 19.)

with its IVC filters, yet deprives Bard from presenting evidence regarding widespread knowledge and acceptance of those risks in the medical community during the relevant time period. It would be fundamentally unjust for Plaintiff's request to be granted.

III. CONCLUSION

For the foregoing reasons, Bard respectfully asks this Court to deny Plaintiffs' Motion.

DATED this 12th day of October, 2022.

Respectfully submitted,

s/ Matthew E. Brown
Matthew E. Brown
Pa. Bar No. 93541
Nelson, Mullins, Riley & Scarborough, LLP
One Financial Center, Suite 3500
Boston MA 02111
(Tel) 617-573-4700
E-mail: matt.brown@nelsonmullins.com

Richard B. North, Jr. (*Pro Hac Vice*)
Elizabeth C. Helm (*Pro Hac Vice*)
Nelson Mullins Riley & Scarborough LLP
201 17th Street NW, Suite 1700
Atlanta, GA 30363
404-322-6000
E-mail: richard.north@nelsonmullins.com
E-mail: kate.helm@nelsonmullins.com

James F. Rogers (*Pro Hac Vice*)
1320 Main Street, 17th Floor
Columbia, SC 29201
Tel: (803) 255-9489
Email: jim.rogers@nelsonmullins.com

Brian T. Feeney
GREENBERG TRAURIG, LLP
1717 Arch Street, Suite 400
Philadelphia, PA 19103

Tel: 215-988-7877
Fax: 215-988-7801
feeneyb@gtlaw.com

Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.